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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,340	03/20/2001	Hiep Huatan	PC10381A	1232
25533	7590	04/12/2005	EXAMINER	
PHARMACIA & UPJOHN 301 HENRIETTA ST 0228-32-LAW KALAMAZOO, MI 49007			HAWES, PILI ASABI	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/813,340

Applicant(s)

HUATAN ET AL.

Examiner

Pili A. Hawes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Action Summary***

Receipt of Applicants Amendments to the claims, filed 1/28/2004 and Applicants Remarks, filed 11/10/2003 is acknowledged.

Upon careful consideration and review the 35 U.S.C. 103(a) rejections of claims 1-11 in view of Ebert are withdrawn.

A new action on the merits of claims 1-4, 6-8, and 11-14 follows.

Claims 1-4, 6-8, and 11-14 are pending in this office action. Claims 1-4, 6-8, and 11-14 are rejected.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Chewable, liquid-filled formulation for oral health care.

The disclosure is objected to because of the following informalities: the parts of the specification are not clearly labeled and the priority statement is missing.

Appropriate correction is required. Please insert headings for Background; Summary; Detailed Description of Invention. Please include a statement referring to the applications or patents for which this invention derives priority.

### ***Claim Objections***

Claims 1, 2, and 12-14 are objected to because of the following informalities: The units of viscosity are represented two ways (mPas or mPa.s.) these representations

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do not agree with each other or with the specification. Appropriate correction is required. Please amend the claims to agree with the units as set forth in the specification (mPa.s.).

Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend on a cancelled claim. See MPEP § 608.01(n). Accordingly, the claim will not be further treated on the merits.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-8, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chau et al. (US 5637313) in view of Friello (US 4250196) as applied to claims 1-4, 6-8, and 11-14 above, and further in view of Goldman (US 3422184).

Chau et al. discloses a soft chewable pharmaceutical dosage form, that is composed of a hydrogenated polysaccharide, namely hydrogenated starch hydrolysate (HSH) or Lycasin® polyol; water soluble bulking agents, such as gum Arabic, sorbitol and xylitol; and various cellulose derivatives, such as methylcellulose, carboxymethylcellulose (cols. 3-4). The chewable matrix described therein could be used to make chewing gums, candy, cough drops, and liquid filled chewing gum or candy, and breath fresheners (col. 5, lines 56-61). This reference does not teach the incorporation of gelatin into the dosage form. Friello addresses this limitation.

Friello discloses a center filled chewing gum composition that incorporated hydrogenated polysaccharides, such as sorbitol, and natural gums, such as carboxymethylcellulose, and gelatin (col.2 40-68). The reference also discloses the incorporation of hydrogenated polysaccharides, such as HSH in combination with sorbitol and gum Arabic resulting in a gum with a "soft, pliable texture superior to sugarless formulation containing no hydrogenated starch hydrolysate." This softness and pliability improves shelf life, and affords "excellent extrusion properties" (col.4 47-56).

Both references teach the incorporation of a liquid fill in the center of the chewable or masticable composition. Both references teach the addition of humectants, flavorants, and colorants. Neither Chau et al. nor Friello specifically teach the use of this chewable liquid filled form to reduce plaque, control gingivitis, or prevent calculus. Goldman et al. teaches a chewable product for cleaning teeth, which is a "unitary mass of cohesive, resilient, edible material" made of gelatin, gum acacia, dental polishing agents, flavorants.

One of ordinary skill in the art would be motivated to form the soft chewable liquid filled dosage form (of Friello) by incorporating hydrogenated polysaccharides, specifically the hydrogenated polysaccharide Lycasin® polyol, the gum Arabic, and the methylcellulose as taught by Chau, to produce a chewable, edible dental cleaning product as taught by Goldman

Furthermore, it is the position of the examiner that the term edible material as defined by the applicant is encompassed by all three of these references, because the products disclosed therein "can be ingested without causing substantial gastrointestinal obstruction, discomfort, or malfunction." The digestibility is a preferred embodiment of the present invention (see page 3, line 16 of the specification), and is not essential to the instant invention, as is expressed by Applicants use of the word "preferably".

The criticality of the physical characteristics of the masticable substance has not been shown, and as such it will not support the patentability of the subject matter. Where the general conditions of a claim are disclosed in the prior art, it is not inventive

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to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F. 2d. 454, 105 USPQ 233, 235 (CCPA 1995).


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes  
Examiner-1615

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600